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Implementation of the international drug control treaties: changes in the scope of control of substances

Changes in the scope of control of substances

Note by the Secretariat

Summary

The present document contains recommendations for action to be taken by the Commission on Narcotic Drugs pursuant to the international drug control treaties. In accordance with article 3 of the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, the Commission will have before it for consideration a proposal from the World Health Organization concerning a recommendation to place acetylfentanyl in Schedules I and IV and to place MT-45 in Schedule I of that Convention.

In accordance with article 2 of the Convention on Psychotropic Substances of 1971, the Commission will have before it for consideration a proposal from the World Health Organization concerning a recommendation to place para-Methoxymethylamphetamine (PMMA) in Schedule I and a recommendation to place α-Pyrrolidinovalerophenone (α-PVP), para-Methyl-4-methylaminorex (4,4'-DMAR) and methoxetamine (MXE) in Schedule II of that Convention. It will also have before it for consideration a recommendation to place phenazepam in Schedule IV of that Convention.

The present document contains comments provided by Governments on economic, social, legal, administrative and other factors relevant to the proposed scheduling under the 1961 Convention and the 1971 Convention.

* E/CN.7/2016/1.

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I. Consideration of the notification from the World Health Organization concerning scheduling under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol

1. Pursuant to article 3, paragraphs 1, 3 and 5 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, the Director-General of the World Health Organization (WHO), in her correspondence dated 7 December 2015, notified the Secretary-General of the United Nations that WHO recommended that acetylfentanyl be placed in Schedule I and Schedule IV of the 1961 Convention. It also recommended that MT-45 be placed in Schedule I of that Convention (see annex for the relevant extract of that notification).

2. In accordance with the provisions of article 3, paragraph 2, of the 1961 Convention, the Secretary-General transmitted to all Governments a note verbale dated 30 December 2015, annexing the notification and the information submitted by WHO in support of that recommendation.

3. As at 19 February 2016, the following 15 Governments had provided comments on economic, social, legal, administrative or other factors relevant to the recommended scheduling of those substances: Algeria, Austria, Colombia, Côte d'Ivoire, Croatia, El Salvador, Germany, Japan, Mexico, Morocco, Poland, Russian Federation, Spain, Switzerland and Turkmenistan.

4. The Holy See also provided comments on economic, social, legal, administrative or other factors relevant to the recommended scheduling of those substances.

5. The Government of Algeria indicated its support for the scheduling recommendations by WHO and reported that existing evidence justified the placement of the substances under international control.

6. The Government of Austria reported that it was facing difficulties in legally regulating new psychoactive substances, including those to be discussed by the Commission on Narcotic Drugs at its fifty-ninth session. While it agreed that effective measures against the increasingly rapid emergence of such substances were important, measures at the national level alone were insufficient and effective cooperation and coordination between all States was crucial. The Government of Austria indicated that it considered it necessary to develop new, tailored instruments and mechanisms to tackle the phenomenon of new psychoactive substances, addressing the issue at its roots, hindering producers and dealers from rapidly replacing one substance by other substances as soon as they were legally placed under control. The New Psychoactive Substances Act of 2012 had pursued a broad generic approach, defining classes of chemical substances, while targeting offences and criminal sanctions at the supply side only (production of new psychoactive substances and their distribution on the consumer market). The law further encouraged open talk about consumption behaviours from a public health perspective. The Government of Austria further reported that those substances recommended for being placed under international control that were not yet covered by the 2012 Act would be incorporated by an amendment.

7. The Government of Colombia reported that none of the substances recommended for international control had approved medical uses in Colombia. The Ministry of Justice and Law had no objection to the scheduling of those substances, as recommended. It further indicated that inclusion of those substances in the 1961 Convention would entail their inclusion in the Criminal Code of Colombia and in national legislation governing their regulation for medical and scientific uses. While forensic laboratories had the capacity to detect those substances, it would be necessary to strengthen the capacities of the police and the judicial and forensic authorities. The Government of Colombia further expressed its hope that placing substances under international control would increase the availability of comprehensive public health measures to address their use in each country, in accordance with resolution 58/5 of the Commission on Narcotic Drugs. Lastly, the Government of Colombia stressed that the scheduling of the recommended substances would represent an opportunity to strengthen international cooperation and critically review the system of classification, evaluation and decision-making for including new substances under international control and, where appropriate, propose any adjustments necessary based on scientific evidence that could be generated once those substances were placed in the schedules, in implementation of resolutions 58/7 and 58/11 of the Commission on Narcotic Drugs.

8. The Government of Côte d'Ivoire indicated that it did not have any recent information on medical or scientific use of the substances recommended by WHO for scheduling. To prevent any illicit traffic and diversion, it agreed to placing those substances under international control.

9. The Government of Croatia reported that no seizures of acetylfentanyl had been notified in Croatia and the substance was not placed under national control. If other countries were to present evidence of wider abuse at the global level, Croatia would support scheduling of that substance. MT-45 was already placed under national control, in Schedule I of the List of Narcotic Drugs and Plants.

10. The Government of El Salvador indicated that it had no records on the use or consumption of those substances. The National Medicines Directorate was of the opinion that there were no economic, social, legal, administrative or other factors relevant to the placing of the substances under international control, and that the substances could be incorporated into the national list of substances or products that required authorization for their production, use, import or licit marketing.

11. The Government of Germany indicated that it had no objections to the scheduling recommendations made by WHO.

12. The Government of Japan reported that acetylfentanyl and MT-45 were controlled as "designated substances" under the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices. If those substances were to be placed under international control, as recommended by WHO, Japan would enhance their regulation and designate them as "narcotics" under the Narcotics and Psychotropics Control Act.

13. The Government of Mexico reported no objection to placing the two substances under international control, as they represented a risk to public health and society and had no recognized therapeutic value. It reported that the national competent authorities had not reported any seizures of those substances, nor found any evidence of their existence in clandestine drug-manufacturing laboratories.

14. The Government of Morocco indicated that it had no objections to the scheduling recommendations made by WHO.

15. The Government of Poland reported that the WHO recommendations on MT-45 would be in conformity with the national Act on Prevention of Drug Addiction of 29 July 2005; however amendments to that legislation would be necessary to adopt the recommendation concerning acetylfentanyl.

16. The Government of the Russian Federation indicated that, according to information received from the Federal Drug Control Service, acetylfentanyl was already included in the list of narcotic drugs, psychotropic substances and their precursors that had been placed under control in the Russian Federation through Order Number 681 of 30 June 1998 of the Government of the Russian Federation.

17. The Government of Spain indicated that, owing to its pharmacological effects similar to morphine and fentanyl, Spain supported the inclusion of acetylfentanyl in Schedule I of the 1961 Convention. In addition, given that it was particularly liable to abuse, its consumption had caused fatalities and there were no relevant economic, social, legal, administrative or other factors identified, Spain also supported its inclusion in Schedule IV of the 1961 Convention. With regard to MT-45, the Government of Spain indicated that it was a synthetic opioid, with effects similar to morphine, posing a threat to public health and society, with no recognized therapeutic value and was being illicitly produced. For those reasons, Spain supported the inclusion of MT-45 in Schedule I of the 1961 Convention.

18. The Government of Switzerland reported that, owing to its potential to cause substantial harm and the fact that it had no medical or industrial use, acetylfentanyl was already under national control and thus it would support adding the substance to Schedule I and IV of the 1961 Convention, as amended. MT-45 was not yet documented in Switzerland and thus not under national control; however Switzerland would have no objection to adding it to Schedule I of the 1961 Convention, as amended.

19. The Government of Turkmenistan indicated that it had no objections to the scheduling recommendations made by WHO.

20. The Holy See reported that, with regard to any economic, social, legal, administrative and other factors related to the possible scheduling of the substances, it had no observations.

Action to be taken by the Commission on Narcotic Drugs

21. The notification from the Director-General of WHO is before the Commission on Narcotic Drugs for its consideration, in accordance with the provisions of article 3, paragraph 3 (iii) and paragraph 5, of the 1961 Convention, which read as follows:

> “3. (iii) If the World Health Organization finds that the substance is liable to similar abuse and productive of similar ill effects as the drugs in Schedule I or Schedule II or is convertible into a drug, it shall communicate that finding to the Commission which may, in accordance with the recommendation of the

World Health Organization, decide that the substance shall be added to Schedule I or Schedule II."

"5. If the World Health Organization finds that a drug in Schedule I is particularly liable to abuse and to produce ill effects (paragraph 3) and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV, the Commission may, in accordance with the recommendation of the World Health Organization, place that drug in Schedule IV."

22. With regard to the decision-making process, the attention of the Commission is drawn to rule 58 of the rules of procedure of the functional commissions of the Economic and Social Council, which stipulates that decisions shall be made by a majority of the members present and voting. On the assumption that all members are present and voting, that means that for a decision to be adopted, an affirmative vote of at least 27 members of the Commission is required.

23. The Commission should therefore decide:

(a) Whether it wishes to include acetylfentanyl in Schedules I and IV of the 1961 Convention or, if not, what other action, if any, might be required;

(b) Whether it wishes to include MT-45 in Schedule I of the 1961 Convention or, if not, what other action, if any, might be required.

II. Consideration of a notification from the World Health Organization concerning scheduling under the Convention on Psychotropic Substances of 1971

24. Pursuant to article 2, paragraphs 1 and 4, of the Convention on Psychotropic Substances of 1971, the Director-General of WHO, in her correspondence dated 7 December 2015, notified the Secretary-General that WHO recommended placing para-Methoxymethylamphetamine (PMMA) in Schedule I of the 1971 Convention. She also notified the Secretary-General that WHO recommended placing α-Pyrrolidinovalerophenone (α-PVP), para-Methyl-4-methylaminorex (4,4'-DMAR) and methoxetamine (MXE) in Schedule II of the 1971 Convention, and phenazepam in Schedule IV of that Convention. (See annex for the relevant extract of that notification.)

25. In accordance with the provisions of article 2, paragraph 2, of the 1971 Convention, the Secretary-General transmitted to all Governments a note verbale, dated 30 December 2015, annexing the notification and the information submitted by WHO in support of its recommendations.

26. As at 19 February 2016, the following 16 Governments had provided comments on economic, social, legal, administrative or other factors relevant to the recommended scheduling of those substances: Algeria, Austria, Chile, Colombia, Côte d'Ivoire, Croatia, El Salvador, Germany, Japan, Mexico, Morocco, Poland, Russian Federation, Spain, Switzerland and Turkmenistan.

27. The Holy See also provided comments on economic, social, legal, administrative or other factors relevant to the recommended scheduling of those substances.

28. The Government of Algeria indicated its support for the scheduling recommendations by WHO and reported that existing evidence justified the placement of those substances under international control.

29. The Government of Austria reported that it was facing difficulties in legally regulating new psychoactive substances, including those to be discussed by the Commission on Narcotic Drugs at its fifty-ninth session. While it agreed that effective measures against the increasingly rapid emergence of such substances were important, measures at the national level alone were insufficient and effective cooperation and coordination between all States was crucial. The Government of Austria indicated that it considered it necessary to develop new tailored instruments and mechanisms to tackle the phenomenon of new psychoactive substances, addressing the issue at its roots, hindering producers and dealers from rapidly replacing one substance by other substances as soon as they were legally placed under control. The New Psychoactive Substances Act of 2012 pursued a broad generic approach, defining classes of chemical substances, while targeting offences and criminal sanctions at the supply side only (production of new psychoactive substances and their distribution on the consumer market). The law further encouraged open talk about consumption behaviours from a public health perspective. The Government of Austria further reported that those substances recommended for being placed under international control that were not yet covered by the 2012 Act would soon be incorporated by an amendment.

30. The Government of Chile indicated that it considered it appropriate to place α-PVP under international control, as recommended by WHO. Given that the substance showed structural similarities and effects to other synthetic cathinones under international control, while having no licit nor industrial use in Chile, it was recommended that it also be placed under national control in Schedule I of Supreme Decree 867 of the Ministry of the Interior and Public Security.

31. The Government of Colombia reported that none of the substances recommended for international control had approved medical uses in Colombia. The Ministry of Justice and Law had no objection to the scheduling of those substances, as recommended by WHO. It further indicated that inclusion of those substances in the 1971 Convention would entail their inclusion in the Criminal Code of Colombia and in national legislation governing their regulation for medical and scientific uses. While forensic laboratories had the capacity to detect those substances, it would be necessary to strengthen the capacities of the police and the judicial and forensic authorities. The Government of Colombia further expressed its hope that placing those substances under international control would increase the availability of comprehensive public health measures to address their use in each country, in accordance with resolution 58/5 of the Commission on Narcotic Drugs. Lastly, the Government stressed that the scheduling of the recommended substances would represent an opportunity to strengthen international cooperation and critically review the system of classification, evaluation and decision-making for including new substances under international control and, where appropriate, propose any adjustments necessary based on scientific evidence that could be

generated once those substances were placed in the schedules, in implementation of resolutions 58/7 and 58/11 of the Commission on Narcotic Drugs.

32. The Government of Côte d'Ivoire indicated that it did not have any recent information on medical or scientific use of the substances recommended by WHO for scheduling. To prevent any illicit traffic and diversion, it agreed to placing those substances under international control.

33. The Government of Croatia reported that para-Methoxymethylamphetamine (PMMA), α-Pyrrolidinovalerophenone (α-PVP), para-Methyl-4-methylaminorex (4,4'-DMAR), methoxetamine (MXE) and phenazepam were already placed under national control, under Schedule I of the List of Psychotropic Substances and Plants.

34. The Government of El Salvador indicated that it had no records on the use or consumption of those substances. The National Medicines Directorate was of the opinion that there were no economic, social, legal, administrative or other factors relevant to the placing of the substances under international control, and that the substances could be incorporated into the national list of substances or products that required authorization for their production, use, import or licit marketing.

35. The Government of Germany indicated that it had no objections to the scheduling recommendations made by WHO.

36. The Government of Japan reported that para-Methoxymethylamphetamine (PMMA) and α-Pyrrolidinovalerophenone (α-PVP) have been strictly controlled nationally as "narcotics" under the Narcotics and Psychotropics Control Act in order to enhance their control since March 2013. Furthermore, the Government of Japan indicated that para-Methyl-4-methylaminorex (4,4'-DMAR) and Methoxetamine (MXE) were controlled as "designated substances" under the Law on Securing Quality, Efficacy and Safety of products including Pharmaceuticals and Medical Devices. If 4,4'-DMAR and MXE were placed under international control, as recommended by WHO, they would be designated as "narcotics" under national law to enhance their control. Phenazepam was not controlled under national legislation, but if it were to be placed under Schedule IV of the 1971 Convention, the Government of Japan would designate it as "psychotropic" under the national Narcotics and Psychotropics Control Act.

37. The Government of Mexico reported no objection to placing the recommended substances under international control, as they represented a risk to public health and society and had no recognized therapeutic use. It reported that the national competent authorities had not registered any seizures of those substances, nor found any evidence of their presence in any type of clandestine drug production laboratory.

38. The Government of Morocco indicated that it had no objections to the scheduling recommendations made by WHO. The Government of Morocco took into account the absence, with the exception of phenazepam, of any recognized therapeutic use of the substances.

39. The Government of Poland reported that the WHO recommendations on para-Methoxymethylamphetamine (PMMA) and methoxetamine (MXE) would be in conformity with the national Act on Prevention of Drug Addiction of 29 July 2005. In accordance with that legislation, α-Pyrrolidinovalerophenone (α-PVP) is listed as a psychotropic substance under group IV-P and therefore amendments to the Act

would be necessary to move the substance to group II. In addition, an appropriate amendment would also be necessary to reflect the recommendation concerning para-Methyl-4-methylaminorex (4,4'-DMAR).

40. The Government of the Russian Federation indicated that, according to information received from the Federal Drug Control Service, PMMA, alpha-PVP, 4,4'-DMAR and MXE were already included in the list of narcotic drugs, psychotropic substances and their precursors that had been placed under control in the Russian Federation through Order Number 681 of 30 June 1998 of the Government of the Russian Federation. In accordance with Russian legislation, phenazepam was included in the general list of medicinal products and had been widely used for medical purposes since the 1970s. There were no data on its abuse for non-medical purposes on a massive scale. It was indicated that the placement of phenazepam under international control, in line with the recommendation of WHO, could limit its use by patients who needed it. According to information from the Ministry of Industry and Trade of the Russian Federation, the finished pharmacological products of phenazepam were produced by six Russian enterprises. For that reason, the Russian Federation considered the inclusion of phenazepam in Schedule IV of the 1971 Convention to be unadvisable.

41. The Government of Spain reported that para-Methoxymethylamphetamine (PMMA) was produced illicitly and its abuse posed a particularly grave concern for public health and society, while having no recognized therapeutic value. Furthermore, α-Pyrrolidinovalerophenone (α-PVP) was a synthetic cathinone producing pharmacologically effects similar to those of methamphetamine and 3',4'-methylenedioxypyrovalerone (MDPV), which are already internationally controlled. Para-Methyl-4-methylaminorex (4,4'-DMAR) was a substance similar to 4-methylaminorex (4-MAR) and aminorex, which were also included in Schedules I and IV of the 1971 Convention. They were being illicitly produced and posed a substantial concern for public health, while having no recognized therapeutic value. With regard to methoxetamine (MXE), the Government of Spain indicated that it posed a considerable risk to public health, had no recognized therapeutic value and had been placed under national control, in Schedule II of Decree 2829/1977. For those reasons, the Government of Spain indicated its support for the scheduling recommendations by WHO.

42. The Government of Switzerland reported that there was no known medical or industrial use of para-Methoxymethylamphetamine (PMMA), the substance was under national control and Switzerland had no objection to adding it to Schedule I of the 1971 Convention. α-Pyrrolidinovalerophenone (α-PVP) and methoxetamine (MXE) had no known medical or industrial use and based on their potential to cause substantial harm, both substances were already under control in Switzerland. For that reason, it would support their placement in Schedule II of the 1971 Convention. With regard to para-Methyl-4-methylaminorex (4,4'-DMAR), given that the substance was not yet documented in Switzerland, it was not under national control; however Switzerland had no objection to adding it to Schedule II of the 1971 Convention. Lastly, the Government of Switzerland indicated that phenazepam was already under national control and thus it would support the recommendation to add it to Schedule IV of the 1971 Convention.

43. The Government of Turkmenistan indicated that it had no objections to the scheduling recommendations made by WHO.

44. The Holy See reported that, with regard to any economic, social, legal, administrative and other factors related to the possible scheduling of the substances, it had no observations.

Action to be taken by the Commission on Narcotic Drugs

45. The notification by the Director-General of WHO is before the Commission on Narcotic Drugs for consideration, in accordance with the provisions of article 2, paragraph 5, of the 1971 Convention, which reads as follows:

> "5. The Commission, taking into account the communication from the World Health Organization, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources."

46. With regard to the decision-making process, the attention of the Commission is drawn to article 17, paragraph 2, of the 1971 Convention, which stipulates that the "decisions of the Commission provided for in articles 2 and 3 shall be taken by a two-thirds majority of the members of the Commission". From a practical point of view, this means that, for a decision to be adopted, an affirmative vote of at least 35 members of the Commission is required.

47. The Commission should therefore decide:

(a) Whether it wishes to place para-Methoxymethylamphetamine (PMMA) under Schedule I of the 1971 Convention or, if not, what other action, if any, might be required;

(b) Whether it wishes to place α-Pyrrolidinovalerophenone (α-PVP) under Schedule II of the 1971 Convention or, if not, what other action, if any, might be required;

(c) Whether it wishes to place para-Methyl-4-methylaminorex (4,4'-DMAR) under Schedule II of the 1971 Convention or, if not, what other action, if any, might be required;

(d) Whether it wishes to place methoxetamine (MXE) under Schedule II of the 1971 Convention or, if not, what other action, if any, might be required;

(e) Whether it wishes to place phenazepam under Schedule IV of the 1971 Convention or, if not, what other action, if any, might be required.

Update on ketamine

48. The Director-General of WHO, in her communication to the Secretary-General, also made reference to decision 58/2 of the Commission on Narcotic Drugs of 13 March 2015, by which the Commission decided to postpone consideration of the proposal concerning the recommendation to place ketamine in Schedule IV of the Convention on Psychotropic Substances of 1971 and to request additional

information from WHO and other relevant sources. The Director-General of WHO in her communication reported that, based on an update review paper on ketamine, the Expert Committee on Drug Dependence unanimously agreed that it had found nothing in the updates, nor in what had been disclosed during its deliberations, that would give it reason to recommend a new pre-review or critical review of ketamine with a view to potentially changing its standing recommendation of 2014 that ketamine should not be placed under international control.

49. The Government of Mexico reiterated its support for the recommendation of WHO on ketamine and reported that the substance was classified as a controlled substance under national legislation, but was not completely prohibited owing to its therapeutic use. Diversion of ketamine for illicit purposes was not common and there was no knowledge of its synthesis in clandestine laboratories.

Annex

Extract of the notification from the Director-General of the World Health Organization to the Secretary-General dated 7 December 2015 concerning the scheduling of substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971, including the relevant extract from the thirty-seventh report of the Expert Committee on Drug Dependence

With reference to Article 2, paragraphs 1, 4 and 6 of the Convention on Psychotropic Substances (1971) and Article 3, paragraphs 1, 3 and 5 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, I am pleased to submit recommendations of the World Health Organization (WHO) as follows:

- Acetylfentanyl be placed in Schedule I and in Schedule IV of the Single Convention on Narcotic Drugs (1961), and that:
- MT-45 be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), and that:
- para-Methoxymethylamphetamine (PMMA) be placed in Schedule I of the Convention on Psychotropic Substances (1971), and that:
- α-Pyrrolidinovalerophenone (α-PVP); para-Methyl-4-methylaminorex (4,4'-DMAR) and methoxetamine (MXE) be placed in Schedule II of the Convention on Psychotropic Substances (1971), and that:
- Phenazepam be placed in Schedule IV of the Convention on Psychotropic Substances (1971).

The recommendations and the assessments and findings on which they are based are set out in detail in the thirty-seventh report of the Expert Committee on Drug Dependence.

In decision 58/2 of 13 March 2015, the Commission on Narcotic Drugs decided to postpone the consideration of the proposal concerning the recommendation to place ketamine in Schedule IV of the Convention on Psychotropic Substances of 1971 and to request additional information from the World Health Organization and other relevant sources. Consequentially, an update review paper on ketamine was commissioned and provided to the Expert Committee. Following its deliberations the Committee unanimously agreed that it found nothing in the updates, nor in what was disclosed during its deliberations, that would give it reason to recommend a new pre-review or critical review of ketamine with a view to potentially change its standing recommendation of 2014 that ketamine should not be placed under international control. The current standing recommendation is consistent with the earlier recommendation made in 2012.

Extract from the thirty-seventh report of the Expert Committee on Drug Dependence

Substance recommended to be scheduled in Schedule I and Schedule IV of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol

Acetylfentanyl

Chemically, acetylfentanyl is *N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidinyl]acetamide. It is in the phenylpiperidine class of synthetic opioids that includes fentanyl, a Schedule I drug under the United Nations 1961 Single Convention on Narcotic Drugs. Acetylfentanyl has also been referred to as "desmethyl fentanyl".

Acetylfentanyl has not been previously reviewed by the Committee. A critical review was proposed based on information brought to WHO's attention that acetylfentanyl is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any Party.

Acetylfentanyl has effects similar to those of morphine and fentanyl that are included in Schedule I of the 1961 Single Convention on Narcotic Drugs. It has no recorded therapeutic use and its use has resulted in fatalities. Thus, because it meets the required condition of similarity, it is recommended that acetylfentanyl be placed in Schedule I of the Single Convention on Narcotic Drugs, 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects as drugs in Schedule I. In addition, in accordance with Article 3, paragraph 5 of that Convention, considering acetylfentanyl is particularly liable to abuse and to produce ill-effects, and its liability is not offset by substantial therapeutic advantages, it is recommended it be included in Schedule IV of the Single Convention on Narcotic Drugs, 1961.

Substance recommended to be scheduled in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol

MT-45

Chemically, MT-45 is 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine. MT-45 has two enantiomers and is commonly available as the racemic mixture.

MT-45 has not been previously reviewed by the Committee. A critical review was proposed based on information brought to WHO's attention that MT-45 is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any Party.

MT-45 is a compound with morphine-like effects. The Committee considered that the degree of risk to public health and society associated with the abuse liability and accompanying evidence warranted its placement under international control. Therapeutic use in humans has not been recorded. The Committee recommended that MT-45 be placed in Schedule I of the 1961 Single Convention, as amended by the 1972 Protocol.

Substance recommended to be scheduled in Schedule I of the Convention on Psychotropic Substances (1971)

para-Methoxymethylamphetamine (PMMA)

Chemically, PMMA (para-methoxymethylamphetamine) is 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine. PMMA has two enantiomers and is commonly available as the racemic mixture.

PMMA has not been previously reviewed by the Committee. A critical review was proposed based on information brought to WHO's attention that PMMA is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any Party.

The Committee considered that the effects of PMMA are similar to PMA, a drug listed in Schedule I of the Convention on Psychotropic Substances of 1971, and the degree of risk to public health and society associated with its abuse is especially serious. The Committee also noted it has no recorded therapeutic use. The Committee considered that the evidence of its abuse warranted its placement under international control and recommended that PMMA be placed in Schedule I of the 1971 Convention.

Substances recommended to be scheduled in Schedule II of the Convention on Psychotropic Substances (1971)

α-Pyrrolidinovalerophenone (α-PVP)

Chemically, α-PVP (α-pyrrolidinovalerophenone) is 1-phenyl-2-(pyrrolidin-1-yl) pentan-1-one.

This synthetic cathinone is the desmethyl analogue of pyrovalerone that is listed in Schedule IV of the 1971 United Nations Convention on Psychotropic Substances. α-PVP has two enantiomers and is commonly available as the racemic mixture. α-PVP is closely related to 3',4'-methylenedioxypyrovalerone (MDPV) that has recently been placed in Schedule II of the United Nations Convention on Psychotropic Substances (1971).

α-PVP has not been previously reviewed by the Committee. A direct critical review was proposed based on information brought to WHO's attention that α-PVP is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any party.

The Committee considered that the degree of risk to public health and society associated with the abuse of α-PVP is substantial. Therapeutic usefulness has not been recorded. Its pharmacological effects are similar to methamphetamine and MDPV, psychostimulants listed in Schedule II of the 1971 Convention. The Committee considered that the evidence of its abuse warranted its placement under international control. As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was accorded to the substantial public health risk than to the lack of therapeutic usefulness. The Committee recommended that α-PVP be placed in Schedule II of the 1971 Convention.

para-Methyl-4-methylaminorex (4,4'-DMAR)

Chemically, 4,4'-DMAR (para-methyl-4-methylaminorex) is 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine. 4,4'-DMAR has four enantiomers and exists as racemic cis- or trans- forms. It is a synthetic substituted oxazoline derivative interpretable as an analogue of 4-methylaminorex (4-MAR) and aminorex, which are psychostimulants listed as Schedule I and Schedule IV substances, respectively, under the 1971 United Nations Convention on Psychotropic Substances.

4,4'-DMAR has not been previously reviewed by WHO. A critical review was proposed based on information brought to WHO's attention that 4,4'-DMAR is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any party.

As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was accorded to the substantial public health risk than to the lack of therapeutic usefulness. The Committee considered that the degree of risk to public health and society associated with the abuse of 4,4'-DMAR is substantial. The Committee recommended that 4,4'-DMAR be placed in Schedule II of the 1971 Convention.

Methoxetamine (MXE)

Chemically, methoxetamine (MXE) is 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexanone. It is a synthetic drug and belongs to the arylcyclohexylamine class like phencyclidine. Methoxetamine has two enantiomers and is commonly available as the racemic mixture.

During its 36th meeting, the WHO Expert Committee on Drug Dependence discussed the critical review report on methoxetamine and concluded that owing to the insufficiency of data regarding dependence, abuse and risks to public health, methoxetamine should not be placed under international control at that time, but be kept under surveillance. In 2014 the European Union decided to bring methoxetamine under control after a risk assessment by the EMCDDA. Furthermore new information on its abuse potential and more reports of fatal and non-fatal intoxications warranted a critical review for the 37th Expert Committee on Drug Dependence (ECDD).

Methoxetamine has been shown to have effects similar to phencyclidine, a compound listed in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that the degree of risk to public health and society associated with the abuse liability of methoxetamine is substantial. The Committee also noted it has no recorded therapeutic use. The Committee considered that the evidence of its abuse warranted its placement under international control. The Committee recommended that methoxetamine be placed in Schedule II of the 1971 Convention.

Substance recommended to be scheduled in Schedule IV of the Convention on Psychotropic Substances (1971)

Phenazepam

Chemically, phenazepam is 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one.

Phenazepam has not been previously reviewed by the Committee. The Committee undertook a pre-review of the substance and considered that the information provided in the pre-review report was sufficient and indicated that dependence and harm caused by phenazepam was of such magnitude that proceeding directly into critical review within the meeting was warranted. All procedural requirements for a critical review, including two peer reviews, were fulfilled. Phenazepam has been shown to have effects similar to diazepam that is in Schedule IV of the Convention on Psychotropic Substances of 1971. The Committee considered that the degree of risk to public health and society associated with the abuse of phenazepam has a smaller but still significant risk to public health compared to substances in Schedules I-III and has a therapeutic usefulness from little to great. The Committee considered that the evidence of its abuse warranted its placement under international control. The Committee further recommended that phenazepam be placed in Schedule IV of the 1971 Convention.

Substance recommended for critical review

Etizolam (INN)

Chemically, etizolam is 4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4] triazolo[4,3-a][1,4]diazepine.

ECDD reviewed etizolam for the first time at its 26th meeting in 1989. At that time, the Committee rated the abuse liability of etizolam as moderate and the therapeutic usefulness as moderate to high. In view of the lack of clear-cut abuse, and of public health and social problems associated with its use, the Committee was unable to come to a decision concerning the scheduling of etizolam and recommended that a decision be deferred to the 27th meeting of the Committee.

At its 27th meeting in 1990, the Committee again rated the abuse liability of etizolam as low to moderate and the therapeutic usefulness as moderate to high. The Committee noted few public health and social problems associated with its use at that time and considered that the degree of seriousness of these problems was not great enough to warrant international control. Consequently, the Committee did not recommend scheduling of etizolam in 1990.

At the 37th ECDD, on the basis of the evidence available regarding dependence, abuse and risks to public health, the Committee recommended that a critical review of etizolam is warranted for a future meeting.

Substance recommended for surveillance

4-Fluoroamphetamine (4-FA)

Chemically, 4-FA (4-fluoroamphetamine) is 1-(4-fluorophenyl)propan-2-amine. 4-FA has two enantiomers and is commonly available as the racemic mixture.

4-FA has not been previously reviewed by the Committee. A critical review was proposed based on information brought to WHO's attention that 4-FA is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any Party.

Owing to the current insufficiency of data regarding dependence, abuse and risks to public health (including risks to the individual), the Committee recommended that 4-FA not be placed under international control at this time, but be kept under surveillance.

Update on cannabis

The Commission on Narcotic Drugs, in resolution 52/5, expressed that it "... looks forward to an updated report on cannabis by the Expert Committee, subject to the availability of extrabudgetary resources", and the Report of the International Narcotics Control Board for 2014 reiterated, "... its invitation to WHO to evaluate the potential medical utility of cannabis and the extent to which cannabis poses a risk to human health". WHO therefore commissioned an update report paper on cannabis and cannabis resin.

An update on the scientific literature of cannabis was presented and reviewed during the session including the pharmacology, toxicology and the claimed therapeutic applications. The Committee then deliberated about the content of the material presented. The Committee requested the Secretariat to begin collecting data towards a pre-review of cannabis, cannabis resin, extracts and tinctures of cannabis at a future meeting. Furthermore it specifically requested the Secretariat to place emphasis on any therapeutic advantages that they may have relative to other existing therapeutics.

Update on ketamine

Updates on ketamine were presented in which the levels and consequences of its abuse, and new potential medical applications were identified. Levels of ketamine abuse appeared to be declining in many countries worldwide. Potential new therapeutic uses were identified including depression and refractory status epilepticus. Evaluation of ketamine for treating depression is in Phase III studies. Ketamine is widely used as an anaesthetic agent for human and veterinary use globally. Ketamine is the anaesthetic agent of choice in low-income countries and emergency situations where there are limitations in trained medical personnel, anaesthesia machines, and consistent sources of electricity.

Following its deliberations, the Committee unanimously agreed that it found nothing in the updates, nor in what had been disclosed during its deliberations, that would give it reason to recommend a new pre-review or critical review of ketamine with a view to potentially change its standing recommendation of 2014 that ketamine should not be placed under international control.